

**Amendment and Response**

Applicant: R. Glen Coleman

Serial No.: 10/600,871

Filed: June 20, 2003

Docket No.: M190.254.101/PD-170.02

Title: FOCUSED ULTRASOUND ABLATION DEVICES HAVING SELECTIVELY ACTUABLE EMITTING ELEMENTS AND METHOD OF USING THE SAME

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**REMARKS**

The following remarks are made in response to the Non-Final Office Action mailed September 11, 2007. Claims 1-27 were rejected. Claims 1-27 remain pending in the application and are presented for reconsideration and allowance.

**Claim Rejections under 35 U.S.C. § 103****The Rejection based on Anderson and Briskin**

Claims 1-3, 9-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. US Patent No. 4,562,900 in view of Briskin et al. US Patent No. 6,575,956. Claims 1 and 9 are independent claims. Claims 2-3 depend from claim 1. Claims 10-12, 14 and 15 depend from claim 9. Applicant here traverses the rejection of the independent claims 1 and 9 and thus the rejection of claims 2-3, 10-12, 14, and 15.

Claim 1 includes the features of "the ultrasound energy is focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element to form a lesion." Claim 1 also includes the features of "the ultrasound emitting elements being selectively, independently actuatable to emit ultrasound energy and being selectively, independently non-actuatable to not emit ultrasound energy."

Also, claim 9 includes the features of "the ultrasound transducer elements selectively, independently actuatable to emit focused ultrasound energy . . . at separate and distinct locations for each individual ultrasound transducer element such that the area . . . is heated by focused ultrasound energy to create the lesion."

Applicant submits that at least the above features of the independent claims are neither shown nor made obvious in the combination of Anderson in view of Briskin.

According to the Office Action on page 4, "Anderson et al. does not explicitly teach that the ultrasound energy is focused at separate and distinct locations for each element or teach selective actuation and de-actuation of the one or more transducer elements." Further, Briskin discloses "a multitude of transducers . . . focused within tissue of the patient at separate and

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distinct locations. These individual transducers may be operated such that their activation is staggered (independently actuatable and selectively independently actuatable)." Applicant respectfully traverses this rejection.

By way of background, the present claims provide for a "focused ablation device for creating a lesion in the patient." Ablation devices, typically known as high intensity focused ultrasound (HIFU) systems are commonly understood in the art as operating with highly focused ultrasound beams that heat tissues to form lesions. This is often known as thermal ablation and is one form of therapy involved in heating tissue. The features of claim 1 include "the ultrasound energy is focused within the tissue . . . to form a lesion" in accordance with thermal ablation. Also, the features of claim 9 include "the tissue adjacent to the active surface is heated by focused ultrasound energy to create the lesion within tissue of the patient."

Briskin specifically avoids the techniques in thermal therapy in general and HIFU systems specifically to create mechanical effects in tissue. The mechanical effects of Briskin fail to produce any significant heating of tissue, in contrast to that set forth in the present claims. Briskin teaches creating mechanical effects using wide beam technology, as opposed to focusing the ultrasound energy. The figures in Briskin show an unfocused beam that slightly converges and then diverges as it leaves the transducer. This is a common effect of unfocused ultrasound beams as interference in the near zone causes the convergences whereas the beam tends to diverge in the far zone. Briskin also teaches using several transducers to widen the beam, such as the device shown in Briskin figure 27 and described in the related text to provide therapy to a field of view larger than one transducers. The purpose of Briskin is wholly different than ablation as it teaches using the mechanical effects of wide beam technology to promote cellular uptake of certain denigratable drugs after injection into tissue prior to denigration of the drug.

Returning to the claims, Applicant respectfully submits that Briskin does not teach the features of "the ultrasound energy is focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element to form a lesion" as set forth in claim 1, and it does not teach the features of "the tissue adjacent to the active face is heated by focused ultrasound energy to create the lesion" of claim 9. In Briskin, there is no focusing of the beams.

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Accordingly, there is no teaching that "the ultrasound energy is focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element" as set forth in claim 1 and that "the ultrasound transducer elements . . . emit focused ultrasound energy" as set forth in claim 9. This is because the Brisken device must apply mechanical therapy instead of thermal therapy in order to achieve its purposes. Additionally, the mechanical therapy in Brisken does not meet the terms of "form a lesion" as set forth in claim 1 or of "create a lesion" as set forth in claim 9.

Further, Brisken does not teach that "the ultrasound emitting elements being selectively, independently actuatable to emit ultrasound energy and being selectively, independently non-actuatable to not emit ultrasound energy" as set forth in claim 1. The device taught in Brisken figure 27 "may be operated such that their activation is staggered," as set forth in Brisken column 16, lines 8-9. This is so that the "system duty cycle can be increased," and "to avoid constructive or destructive interference between their respective ultrasound beam." Brisken, column 16, lines 11-17.

The staggered feature of Brisken does not provide for "selectively, independently non-actuatable" transducers as set forth in claim 1 and "ultrasound transducer elements selectively, independently actuatable to emit focused ultrasound energy" as set forth in claim 9. In Brisken, the staggered pattern is predetermined at manufacture to provide for the ultimate wide beam path to optimized design characteristics of duty cycle and interference. These are related to the design of the item, not toward independent use. Also, all of the transducers are operated in each duty cycle to give the effect of a wide beam exposure for each duty cycle. By operating each transducer during the duty cycle, the device of Brisken cannot provide for "a lesion of selected size and configuration is formed in accordance with the positions of the ultrasound emitting elements selected to be actuated" as in claim 1. Within the short time of each duty cycle of Brisken, the same wide beam is provided each duty cycle and the size and configuration of the beam is not selectable.

Because these claimed features are missing from Anderson and Brisken separately, they cannot be found in any proposed combination of the references. Accordingly, Applicant

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respectively submits that independent claims 1 and 9 are patentably distinguishable over the combination of Anderson in view of Brisken. Further, by virtue of their dependency, claims 2-3, 10-12, 14 and 15 are patentably distinguishable over the combination of Anderson in view of Brisken.

**The Rejection based on Anderson in View of Brisken and in Further View of Castel**

Claims 4, 6-8, 13, 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. US Patent No. 4,562,900 in view of Brisken et al. as applied to claims 1 and 9 above, and further in view of Castel US Patent No. 5,413,550. Claims 4 and 6-8 depend from independent claim 1, which is patentably distinguishable from the combination of Anderson in view of Brisken. Similarly, claims 13, 16, and 18-20 depend from independent claim 9, which is also patentably distinguishable from the combination of Anderson in view of Brisken. Castel has been cited to diagram "the specifics of the handle as disclosed in Applicant's claims" as set forth in the Office Action at page 5. Castel does not teach or make obvious the deficiencies of the Anderson and Brisken combination in view of claims 1 and 9 described above. Accordingly, the features set forth in claims 1 and 9 are not found in the combination of Anderson in view of Brisken and in further in view of Castel either. Thus, the dependent claims 4, 6-8, 13, 16, and 18-20 are patentably distinguishable from the combination of Anderson in view of Brisken and further in view of Castel.

**The Rejection based on Anderson in View of Brisken and in Further View of Weng**

Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson US Patent No. 4,562,900 in view of Brisken et al. US Patent No. 6,575,956 as applied to claims 1 and 9 above and further in view of Weng et al. US Patent No. 6,626,855. Claim 5 depends from independent claim 1, which is patentably distinguishable from the combination of Anderson in view of Brisken. Similarly, claim 17 depends from independent claim 9, which is also patentably distinguishable from the combination of Anderson in view of Brisken. The

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Office Action states that the combination of Anderson and Brisken do not provide for "the malleability of the handle shaft of the ultrasound therapeutic device." Weng has been cited to diagram "diagram the flexible portion (ref. no. 31) of the handle shaft" as set forth in the Office Action at page 5. Weng does not teach or make obvious the deficiencies of the Anderson and Brisken combination in view of claims 1 and 9 as described above. Accordingly, the features set forth in claims 1 and 9 are not found in the combination of Anderson in view of Brisken and in further in view of Castel either. Thus, the dependent claims 5 and 17 are patentably distinguishable from the combination of Anderson in view of Brisken and further in view of Weng.

**The Rejection based on Anderson in view of Castel and in further View of Brisken**

Claims 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson US Patent No. 4,562,900, in view of Castel US Patent No. 5,413,550 and further in view of Brisken et al. US Patent No. 6,575,956. In claims 21-27, claim 21 is an independent claim, and claims 22-27 depend from claim 21. Applicant respectfully traverses the rejection of claims 21-27.

Claim 21 includes the features of "focusing the ultrasound energy with the selected one or more of the ultrasound emitting elements so that the ultrasound energy is . . . focused at separate and distinct locations for each individual ultrasound emitting element." This feature is not shown or made obvious in Anderson. As set forth in the Office Action at page 4, "Anderson et al. does not explicitly teach that the ultrasound energy is focused at separate and distinct location for each element." Accordingly, this feature of claim 21 is not found in Anderson. As described above with respect to claims 1 and 9, Brisken also does not teach or make obvious "focusing the ultrasound energy . . . at separate and distinct locations" because Brisken does not focus the elements. Castel does not teach these features either.

Because the features of "focusing the ultrasound energy with the selected one or more of the ultrasound emitting elements so that the ultrasound energy is . . . focused at separate and distinct locations for each individual ultrasound emitting element" of independent claim 21 are

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not shown in Anderson, Briskeen or Castel separately, they cannot be found in any proposed combination of the references. Accordingly, independent claim 21 and its dependent claims 22-27, by virtue of their dependency, are patentably distinguishable from the combination of Anderson in view of Castel and in further view of Briskeen.

**The Rejection Based on Anderson in View of Iinuma and in Further View of Kimura**

Claims 1-3, 9-12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. US Patent No. 4,562,900 in view of Iinuma US Patent No. 5,448,994 and further in view of Kimura US Patent No. 5,402,792. As mentioned above, claims 1 and 9 are independent claims. Claims 2-3 depend from claim 1. Claims 10-12, 14 and 15 depend from claim 9. Applicant here traverses the rejection of the independent claims 1 and 9 and thus the rejection of claims 2-3, 10-12, 14, and 15.

Claim 1 includes the features of "the ultrasound energy is focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element to form a lesion." Claim 1 also includes the features of "the ultrasound emitting elements being selectively, independently actuatable to emit ultrasound energy and being selectively, independently non-actuatable to not emit ultrasound energy." Also, claim 9 includes the features of "the ultrasound transducer elements selectively, independently actuatable to emit focused ultrasound energy . . . at separate and distinct locations for each individual ultrasound transducer element such that the area . . . is heated by focused ultrasound energy to create the lesion."

Applicant submits that at least the above features of the independent claims are neither shown nor made obvious in the combination of Anderson in view of Iinuma and further in view of Kimura.

Anderson teaches a lens system for focusing a plurality of transducer elements to a single point. Anderson is deficient in its teaching that it "does not explicitly teach that the ultrasound energy is focused at separate and distinct location for each element." Further, Anderson does not

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teach or make obvious that the transducer elements are "selectively, independently actuatable" as set forth in independent claims 1 and 9.

Linuma teaches a system where a plurality of transducers are focused at a single point, but some of the transducers can be reduced in power to avoid tissues that may be in the way of a particular transducer's transmission. Linuma does not teach focusing at separate and distinct locations for each elements." Further, Linuma does teach that the transducer elements are "selectively, independently actuatable" as set forth in claims 1 and 9. The transducers in Linuma are automatically actuated and only in response to feed back as to particular tissue in the way of the transmission.

Kimura teaches a medical apparatus with an acoustic lens so that the emitted ultra sonic waves are focused at two or more different positions. Because of the fixed nature of the acoustic lens, Kimura does not teach that the waves emitted from the transducer can be "selectively, independently actuatable" as set forth in claims 1 and 9. Further, there is no teaching that the transducer in Kimura is extended to more than one in contrast to the requirement of "transducer elements" set forth in claims 1 and 9. This feature is not made obvious because there is no mention of how to collectively focus the lenses if apparatus of Kimura did include "transducer elements." Even so, there is no teaching or suggestion that a plurality of transducers, even if they were to exist, be "selectively, independently actuatable" as required in the claim.

Because the features of "the ultrasound energy is focused within tissue of the patient at separate and distinct locations for each individual ultrasound emitting element to form a lesion" and "the ultrasound emitting elements being selectively, independently actuatable to emit ultrasound energy and being selectively, independently non-actuatable to not emit ultrasound energy" of claim 1; and the features of "the ultrasound transducer elements selectively, independently actuatable to emit focused ultrasound energy . . . at separate and distinct locations for each individual ultrasound transducer element such that the area . . . is heated by focused ultrasound energy to create the lesion" of claim 9 are not taught or made obvious in Anderson, Linuma, and Kimura separately, they cannot be found in any proposed combination of the

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references. Accordingly, independent claims 1 and 9 and also rejected dependent claims 2-3, 10-12, 14 and 15, by virtue of their dependency, are patentably distinguishable from the prior art.



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**CONCLUSION**

In view of the above, Applicant respectfully submits that pending claims 1-27 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-27 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Rudolph P. Hofmann at Telephone No. (612) 573-2010, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

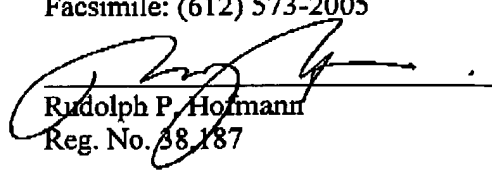
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Respectfully submitted,

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**CERTIFICATE UNDER 37 C.F.R. 1.8:** The undersigned hereby certifies that this paper or papers, as described herein, are being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (571) 273-8300 on this 11<sup>th</sup> day of December, 2007.

By 

Name: Rudolph P. Hofmann